Translation

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference | FOR FURTHER ACTION | See Form PCT/IPEA/416 |
|---|---|---|
| Brt/VI/1/03 | | |
| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
| PCT/EP2004/003567 | 03.04.2004 | 08.04.2003 |
| International Patent Classification (IPC) or national classification and IPC | | |
| Applicant | | |
| SCHWARZ PHARMA AG | | |

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 9 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☒ *(sent to the applicant and to the International Bureau)* a total of 7 sheets, as follows:

      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))

      _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

| | | |
|---|---|---|
| ☒ | Box No. I | Basis of the report |
| ☒ | Box No. II | Priority |
| ☒ | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| ☐ | Box No. IV | Lack of unity of invention |
| ☒ | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| ☐ | Box No. VI | Certain documents cited |
| ☐ | Box No. VII | Certain defects in the international application |
| ☒ | Box No. VIII | Certain observations on the international application |

| Date of submission of the demand | Date of completion of this report |
|---|---|
| Name and mailing address of the IPEA/EP | Authorized officer |
| Facsimile No. | Telephone No. |

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/003567

**Box No. I Basis of the report**

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

☐ international search (Rule 12.3 and 23.1(b))

☐ publication of the international application (Rule 12.4)

☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ the international application as originally filed/furnished

☒ the description:

pages 1-50 as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☒ the claims:

nos. _____ as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* 1-34 received by this Authority on 02.11.2004 with letter of 28.10.2004

nos.* _____ received by this Authority on _____

☒ the drawings:

sheets 1-4 as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

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**Box No. II Priority**

1. ☒ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:

   ☒ copy of the earlier application whose priority has been claimed (Rule 66.7(a)).

   ☐ translation of the earlier application whose priority has been claimed (Rule 66.7(b)).

2. ☐ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rule 64.1). Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

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**Box No. III** **Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 18,19( in part), 32,34(in part)

because:

☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 18,19(in part),32,34

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

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**Box No. V** **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Claims | 7-15, 17, 19 , 21-27, 33 | YES |
| | Claims | 1-6, 16, 20, 28-31, 34 | NO |
| Inventive step (IS) | Claims | 7-15, 17, 19 , 21-27, 33 | YES |
| | Claims | 1-6, 16, 20, 28-31, 34 | NO |
| Industrial applicability (IA) | Claims | 1-17, 19-31, 33 | YES |
| | Claims | | NO |

2. Citations and explanations (Rule 70.7)

1. The present report refers to the following documents:

D1: WO 99/58478 A
D2: WO 01/35957 A
D3: WO 00/12070 A.

2. Novelty

The present application does not satisfy the requirements of PCT Article 33(1) because the subject matter of claims 1-6, 17, 21, 29-32 and 35 is not novel within the meaning of PCT Article 33(2).

Document D1 discloses compounds of the general formula (I) according to claim 1, **which are 90 to 99% pure** (see example 3aa, in particular page 60, lines 13-15, and page 62) and their use for the treatment of incontinence (see the abstract and pages 35-36). The subject matter of claims 1-6, 16, 20, 28-31 and 34 is therefore not considered novel.

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The method according to claim 7 is not suggested by documents D1 and D2 and is therefore likewise considered novel.

3 Inventive step

According to the application the aim of the invention (see the description, page 3, line 29, to page 4, line 2) is to provide high-purity, free bases of 3,3-diphenylpropylamines of formula (I), which are suitable for transdermal or transmucosal use.

Document D1 already discloses high-purity, free bases of 3,3-diphenylpropylamines suitable for transdermal use and document D2 (see pages 2-3 and 28-32) discloses the crystalline salts of formula (II), presenting high stability and high purity.

The method according to the novel claim 7 is not suggested by the teaching of documents D1 and D2 and therefore considered inventive.

**Box No. VIII** **Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The expression "*suitable* release reagent" used in claim 7 is vague and unclear and leaves the reader in doubt as to the meaning of the corresponding technical feature (release reagent). As a result, the definition of the subject matter of this claim is unclear (PCT Article 6).

The release agent should be clarified according to claim 8.

In addition, an unclear expression cannot be used if this expression, as in the present case, is essential for the delimitation of the invention with respect to the prior art with regard to novelty and inventive step.

**Supplemental Box**

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:

Box III

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. Claim 34 relates to a subject matter which, in the opinion of the Examining Authority, falls under PCT Rule 67.1(iv). Consequently, no opinion with regard to industrial applicability is established in respect of this subject matter (PCT Article 34(4)(a)(i)).

2. The valid claims 18 and 19 (in part) are directed to a product which is defined by means of the following parameter: P1: stabilizing factor (equals to at least 2).

In the present context the use of this parameter would appear to constitute a lack of clarity within the meaning of PCT Article 6. It is not possible to compare the parameter chosen by the applicant with the relevant disclosure in the prior art. The lack of clarity is such that it makes it impossible to carry out a full, meaningful search. Consequently, no examination can be carried out. Claim 19 is dependent on claim 18 and contains an additional parameter. The search of claim 19 was therefore restricted to a product having this parameter.

3. The valid claim 32 relates to a use, characterized by a desirable property, that is to say, a polymer layer which delivers fesoterodine through human skin at a flux

Supplemental Box

rate of 3-15 mg/day. The claim therefore comprises all uses having this property, whereas the description of the application supports only a limited number of such products (PCT Article 5). In the present case the claims lack the proper support and the application lacks the requisite disclosure to such an extent that it does not appear possible to carry out a meaningful search covering the entire range of protection sought. In addition, the claim also lacks the clarity required under PCT Article 6, since it attempts to define the use in terms of the result to be achieved. The lack of clarity is such that a full, meaningful search is not possible. Consequently, no examination is possible.